Radiation Rulemaking & X-Ray Rule Updates



Regulatory Conference September 2014

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Radiation Rule Development Program
Policy, Standards and Quality Assurance Unit

Rulemaking Triggers



- Legislation
- Compatibility
- Public Health & Safety
- Security
- 4 Year Review

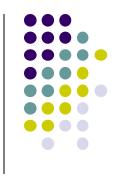




Rule process takes 18 to 20 months

- Working Paper
- Draft Rule
- Proposed Rule
- Adoption of Final Rule

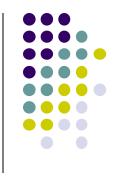




- Working Paper
 - For new rules or extended staff review/discussion

- Vetted through in-house staff only
- Staff perspective essential

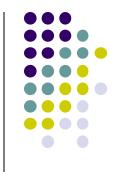




Draft rule

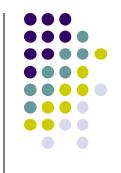
- Email notification to Stakeholders for review/input
- Available on Radiation Program Rule web page
- Stakeholder and Staff perspective essential
- Staff review/discuss comments received to make determination of suggested changes





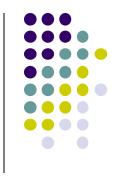
- Proposed Rule
 - Formal comment period & public meeting
 - Email notification to Stakeholders for review/input
 - Available on Radiation Program Rule web page
 - Staff review/discuss comments received to make determination of suggested changes
 - Response to comments via Adoption Preamble
 - Stakeholder and Staff perspective essential





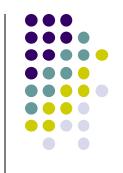
- Proposed Rule Vetted Through:
 - Division of Regulatory Services Management
 - Program Attorney
 - Texas Radiation Advisory Board
 - State Health Services Council
 - Executive Commissioner of the Health & Human Services Commission





- Adoption of Final Rule
 - Too late for substantive changes
 - Published in Texas Register, becomes effective
 20 days after filing or later projected date
 - Email notification to Stakeholders & Staff
 - Available on Radiation Program Rule web page



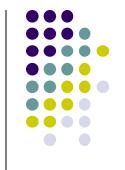


Revised rules are either:

- Amendments
- Repeal and New
- New







Rules with Amendments

The Agency is seeking your input regarding the following noted suggested rule changes. These suggested changes are NOT final rule changes.

Legend: (Draft/Proposed Amendment(s))

<u>Single Underline</u> = Draft/Proposed new language

[Bold, Print, and Brackets] = Current language drafted/proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision





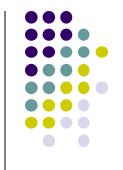


Sample Rule Text with Amendments

- (d) Exemptions.
 - (1) (No change.)
- (2) Individuals who are sole <u>physicians</u>, [**practitioners and**] sole operators and the only occupationally exposed individual are exempt from the following requirements:
 - (A) (No change.)
 - (B) subsection (h)(1)(G)[(h)(1)(D)] of this section.







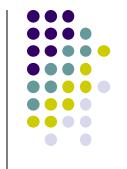
Rules that are Repeal/New OR New

The Agency is seeking your input regarding the following noted suggested rule changes. These suggested changes are NOT final rule changes.

Legend: (Draft/Proposed New Rule(s))

Regular Print = Draft/Proposed new language





Sample Rule Text for Repeal/New OR New

(a) Purpose.

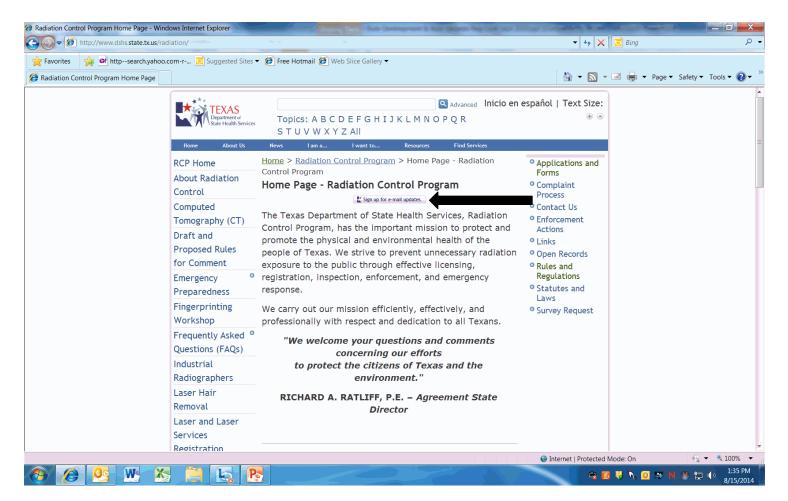
(1) This section provides for the registration of persons using radiation machines and persons who are in the business of providing radiation machine services.

(2) A person who receives, possesses, uses, owns, or acquires radiation machines prior to receiving a certificate of registration is subject to the requirements of this chapter.



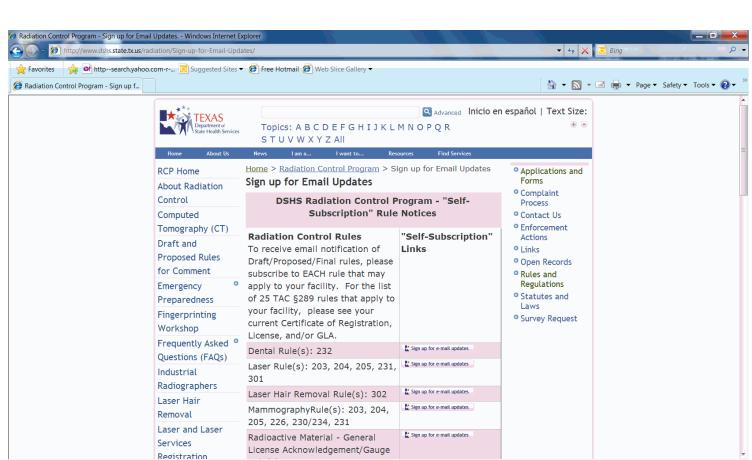
DSHS Rule Notification System

- Free Email self-subscription on Radiation Program Home web page (see Instructions hand-out)
- Notification of comment periods for Draft and Proposed rules
- Notification of Final rules









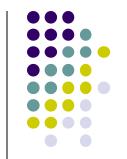




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Since 2010 Regulatory Conference

5 Radiation rules have been revised that impact most Registrants:

25 TAC, §289.229

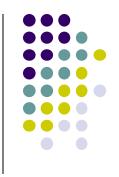
25 TAC, §289.226

25 TAC, §289.231

25 TAC, §289.227

25 TAC, §289.204





25 Texas Administrative Code, §289.229 Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices

Rule Effective Date: December 29, 2011

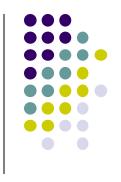




25 Texas Administrative Code, §289.231 General Provisions and Standards for Protection Against Machine-Produced Radiation

Rule Effective Date: December 29, 2011

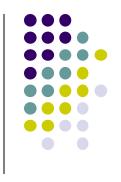




25 Texas Administrative Code, §289.204
Fees for Certificates of Registration,
Radioactive Material Licenses, Emergency
Planning and Implementation, and Other
Regulatory Services

Rule Effective Date: January 1, 2012

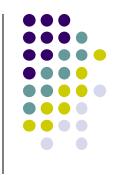




25 Texas Administrative Code, §289.227
Use of Radiation Machines in the Healing Arts

Rule Effective Date: May 1, 2013





25 Texas Administrative Code, §289.226 Registration of Radiation Machine Use and Services

Rule Effective Date: December 17, 2013



Status of X-Ray Rule Revisions

No x-ray rules being revised at present time

Future revisions of 2 x-ray rules pending to incorporate applicable changes made to §\$289.204, 289.226, 289.227, & 289.231:

§289.232 (Dental)

§289.233 (Vet)



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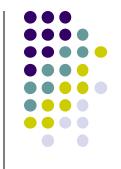
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Radiation Program Web Pages



Home

http://www.dshs.state.tx.us/radiation

Rules

http://www.dshs.state.tx.us/radiation/rules.shtm





Questions?

